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THE FORUM FOR THE FRESH PRODUCE INDUSTRY

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COMMENTS ON FDA PROPOSALS FOR

THE REGISTRATION OF FOOD FACILITIES - FED REG 3 FEB 2003 (DOCKET N° 02N-0276)
THE PRIOR NOTIFICATION OF FOOD IMPORTS - FED REG 3 FEB 2003 (DOCKET N° 02N-0278)

Dear Sir or Madam

Freshfel Europe - The European Fresh Produce Association represents the interests of European exporters, importers, wholesalers and retailers in the fresh fruit and vegetables sector.

Freshfel Europe very much welcomes the opportunity to submit comments on the above-mentioned FDA proposals implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act).

Freshfel Europe fully understands the FDA's aim to enhance the security of the US food supply in view of recent potential terrorist threats. We are, however, highly concerned about the potential trade - distorting effects of the implementation of the Bioterrorism Act, and in particular the requirements for the registration of food facilities and prior notification of food imports into the US as published in the Fed Reg of 3 February 2003.

Registration of Food Facilities + Prior Notification of Food Imports : The proposals as published in the Fed Reg of 3 February do not specify when a registration or notification will be considered incomplete or inadequate i.e. there are no fixed criteria to determine when a registration or notification is to be accepted by the FDA. It is thus unclear what would happen in the case of unintentional errors or omissions e.g. a wrong telephone number or email address. For reasons of legal transparency and predictability, we propose that the FDA includes in its proposals detailed information on what type of errors or omissions may lead to the refusal of the registration or notification by the FDA.

Registration of Food Facilities + Prior Notification of Food Imports : From the proposals as published in the Fed Reg of 3 February it follows that the FDA must examine every submission for registration / notification, determine whether or not it is adequate, inform the customs authorities about the acceptance / refusal of the submission, etc. The European fresh produce trade is extremely concerned about how much time the administrative processing of each registration / notification will require, considering that fresh fruit and vegetables are highly perishable products that require quick customs clearing. We therefore propose that the FDA sets up a 'fast track' procedure for the processing of submissions for registration / notification of fresh fruit and vegetables whereby any reduction in the commercial value of the products due to unnecessary delays at the border would be avoided.

Registration of Food Facilities + Prior Notification of Food Imports : The proposals as published in the Fed Reg of 3 February do not specify what happens in the case of a 'suspect' shipment. Will the FDA inspect samples of 'suspect' shipments before they enter the US market, or will the information merely be used afterwards i.e. when a food crisis has occurred ? If the proposals are merely aimed at tracing the source of the food *after* a crisis has occurred, we question their usefulness in terms of preventing a terrorist attack !

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EUROPEAN FRESH PRODUCE ASSOCIATION A.I.S.B.L

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Registration of Food Facilities : From the proposal as published in the Fed Reg of 3 February it is not absolutely clear to whom the requirement to register applies. We understand from the proposal that the grower is exempt from registration (III.A. 6th bullet point + III.B.3.d) but are unclear whether or not the same exemption applies to entities further down the chain that are not the final holders of the merchandise (e.g. packing stations, wholesale facilities, logistic services providers). We very much doubt the capability of such entities, and especially small-scale operators, to contract a US agent - let alone register themselves. We therefore propose that the requirement to register with the FDA is limited to the last holder of the goods.

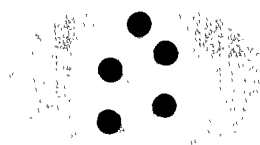
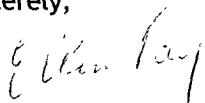
Prior Notice : We are unclear about whether or not a notification has to be made for each article of food from a different grower. On the one hand, the proposal states that 'if a product is sourced from more than one grower, the prior notice must provide the identification of all growers, *if known*' (C.4.g). (How strict is 'if known' ?) On the other hand, the proposal states that the requirement to notify 'applies to each article of food' whereby 'each article of food' means 'each article of food produced by each manufacturer' (C.4). The requirement to notify each article from each manufacturer would impose severe constraints on European fresh produce exports to the US in view of the European fresh produce production structure, whereby a single shipment can consist of dozens of lots, each of them sourced from dozens of different growers.

Prior Notice : The European fresh produce trade is highly concerned about the ability of the FDA to rapidly process the notifications it will receive. We understand that the US customs system will be modified in 2005-2006 to create an Automated Commercial Environment whereby the prior notice would be integrated automatically into the customs declaration. Until that date, however, exporters will have to make a declaration to customs *and* submit a notification to the FDA - separately. Do we have any guarantees that the processing of notifications by the FDA and the transmission of data from the FDA to the customs authorities will function efficiently ? We must reiterate that fresh fruit and vegetables are highly perishable products that require rapid customs clearing. We therefore ask the FDA to create a separate, 'fast track' procedure for the processing of notifications for highly perishable products such as fresh produce to avoid a backlog of fresh produce notifications in the administrative treadmill. In addition, we suggest to create a risk-based system for the notification of shipments whereby regular, trustworthy traders - to be identified on the basis of a prefixed set of objective criteria - are exempt from the requirement to notify each shipment to the US.

Freshfel Europe is closely monitoring every development regarding the finalising of both regulations and would be pleased to work with the FDA to improve the proposals in view of the above remarks. We are convinced that the FDA shares our concern to avoid any impediments of EU - US trade flows, which would not only affect European traders, but also imperil the provision of the US consumer with fresh fruit and vegetables from the EU.

Yours sincerely,

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